Governors not later than October 17, 2016.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *First State Bancshares, Inc., New London, Wisconsin;* to merge with Rudolph Bancshares, Inc., and thereby indirectly control Farmers and Merchants Bank, both of Rudolph, Wisconsin.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) One Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Goering Management Company, LLC, and Goering Financial Holding Company Partnership, LP, both of Moundridge, Kansas;* to acquire additional shares, for a total ownership up to 65 percent of the voting shares, of Bon, Inc., parent of The Citizens State Bank, both in Moundridge, Kansas.

C. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. *Regal Bancorp Inc., Livingston, New Jersey;* to become a bank holding company by acquiring 100 percent of the outstanding stock of Regal Bank, Livingston, New Jersey.

Board of Governors of the Federal Reserve System, September 16, 2016.

Margaret M. Shanks,

Deputy Secretary of the Board.

[FR Doc. 2016–22733 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than October 5, 2016.

A. *Federal Reserve Bank of Kansas City* (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Kara L. Marshall Kelley, Omaha, Nebraska; as trustee of various trusts, and Kristen L. Marshall Maser, Grand Island, Nebraska, as trustee of various trusts, William W. Marshall III 2006 Irrevocable Life Insurance Trust; the 2016 Sharon Marshall Irrevocable HBC Trust; and HBC Investments, LLC; all of Grand Island, Nebraska; and for approval as a member of the Marshall Family Group: Sharon L. Marshall, Matthew Maser, the William W. Marshall III Revocable Trust, the Sharon L. Marshall Irrevocable Dynasty Trust, the Kristen L. Marshall Maser Revocable Trust, the Katherine Marshall Maser Irrevocable Trust, the Carolyn Marshall Maser Irrevocable Trust, the William Marshall Maser Irrevocable Trust, all of Grand Island, Nebraska; and Thomas O. Kelley, the Kara L. Marshall-Kelley Revocable Trust, the Kathleen Grace Kelley Irrevocable Trust, the Thomas O. Kelley Irrevocable Trust, the John Marshall Kelley Irrevocable Trust, all of Omaha, Nebraska;* to acquire shares of and Hometown Banc Corp, Grand Island, Nebraska, and thereby control Five Points Bank, Grand Island, Nebraska, and Five Points Bank of Hastings, Hastings, Nebraska.

B. *Federal Reserve Bank of Dallas* (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Mickey Wiley Carter, Sr., as co-trustee of Carter Holdings Trust, both of Omaha, Texas;* to join the Holton Family Group and to retain control of the voting shares of WSB Bancshares, Inc., Wellington, Texas, and indirectly retain shares of Wellington State Bank, Wellington, Texas.

Board of Governors of the Federal Reserve System, September 15, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–22636 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 14, 2016.

A. *Federal Reserve Bank of Philadelphia* (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org*:

1. *HV Bancorp, Inc., Huntingdon, Pennsylvania;* to become a bank holding company by acquiring 100 percent of Huntingdon Valley Bank, Huntingdon, Pennsylvania, upon its conversion to a stock savings bank.

Board of Governors of the Federal Reserve System, September 15, 2016.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–22637 Filed 9–20–16; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Unaccompanied Refugee Minors Placement and Outcomes Reports; ORR–3 and ORR–4.

OMB No.: 0970–0034.

Description: As required by section 412(d) of the Immigration and Nationality Act, the Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), is requesting the information from report

Form ORR–3 and ORR–4 to administer the Unaccompanied Refugee Minors (URM) program. The ORR–3 (Placement Report) is submitted to ORR by the State agency at the minor's initial placement in the resettlement State within 30 days of the placement, and whenever there is a change in the minor's status, including termination from the program, within 60 days of the change or closure of the case. The ORR–4 (Outcomes Report) is submitted every 12 months beginning on the 12 month anniversary date of initial placement to record outcomes of the child's progress toward the goals listed in the child's case plan. An ORR–4 is also submitted along with the initial ORR–3 report for minors 17 years old or above to establish a baseline of information for the youth related to independent living and/or educational plans. The ORR regulations per 45 CFR 400.120 describe specific URM program reporting requirements.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–3	15	Estimated responses 178	0.25 (15 min)	Estimated 667.5.
ORR–4	15	Estimated responses 127	1.5 (1 hour and 30 min)	Estimated 2,857.5.
Estimated Total Annual Burden Hours.				3,525.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, email: *OIRA_SUBMISSION@OMB.EOP.GOV*. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–22678 Filed 9–20–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2730]

Food and Drug Administration's Application of Statutory Factors in Determining When a Risk Evaluation and Mitigation Strategy Is Necessary; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''FDA's Application of Statutory Factors in Determining When a REMS Is Necessary.'' This draft guidance is intended to clarify how FDA applies the factors set forth in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) in determining whether a risk evaluation and mitigation strategy (REMS) is necessary to ensure that the benefits of a drug outweigh its risks. This guidance is one of several being developed to fulfill performance goals that FDA agreed to satisfy in the context of the fifth reauthorization of the prescription drug user fee program (the Prescription Drug User Fee Act V).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 21, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments,